APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,725	10/04/2000	Robert g. Whirley	24641-1070	7345

60117   7590   12/06/2007
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ART UNIT	PAPER NUMBER
2123	

MAIL DATE	DELIVERY MODE
12/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	09/679,725	WHIRLEY ET AL.
	Examiner	Art Unit	
	Jason Proctor	2123	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-123* is/are pending in the application.

   4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

   Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

   Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   a)☐ All   b)☐ Some * c)☐ None of:

   1.☐ Certified copies of the priority documents have been received.

   2.☐ Certified copies of the priority documents have been received in Application No. _____.

   3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

   * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
   Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 were rejected in the Office Action of 11 June 2007.

Applicants have submitted arguments for consideration on 11 October 2007.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 are rejected.

Response to Arguments – 35 USC § 102

1.   In response to the previous rejection of claims 1, 16, 31, 54, 70, and 86 under 35 U.S.C. § 102 as being anticipated by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element Models" by Santosh G. Zachariah and Joen E. Sanders, Applicants argue primarily that:

[The Zachariah reference fails to teach the claimed limitation "simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device."] Zachariah explains in the right hand column of page 289 that "external forces and displacements and internal constraints – collectively called the boundary conditions are applied at appropriate nodes within the mesh." The inputs define only the boundary conditions which are applied at only select nodes. The inputs do not simulate an interaction between the said anatomical features and said medical device to determine the predicted stresses, strains, and deformation of said medical device.

The Examiner respectfully traverses this argument as follows.

Zachariah discloses at least the following portions which are especially relevant to the limitations at issue:

The distribution of mechanical stress at the interface between a residual limb and prosthetic socket is an important design consideration in lower-limb prosthetics. [...] Numerical estiimation of the stresses at the interface through finite element (FE) modeling can potentially provide researchers and prosthetists with a tool to aid in the design of the prosthetic socket. (abstract)

The object of the socket shaping process is to optimally distribute the interface stresses between the residual limb and socket while providing adequate stability and efficient control of the prosthesis. [...] Potentially, computer-aided design in prosthetics can be extended from its current level to allow estimation of the interface stresses for proposed socket designs. (page 288, right column)

To generate the [finite element] model, the geometry of the object of interest is first discretized into small regularly-shaped polygonal finite elements; the elements altogether make up the FE mesh. The vertices of the elements are called nodes, and these are shared by adjacent elements. Properties, such as stress behavior under strain, are then assigned to each element. Finally external forces and displacements and internal constraints – collectively called the boundary conditions – are applied at appropriate nodes within the mesh. (page 289, right column).

Nonlinear boundary conditions at the interface between the residual limb and the

prosthetic socket may also be specified. (page 298, right column)

Therefore Zachariah discloses that boundary conditions are applied <u>at appropriate nodes</u>

because not every node forms a <u>boundary</u> between the prosthetic and the residual limb. Contrary

to Applicants' allegations, it is precisely these boundary conditions that are used to simulated

"interaction between said anatomical feature(s) [the residual limb] and said medical device [the

prosthesis] to determine the predicted stresses, strains, and deformations of said medical device."

Applicants' arguments have been fully considered but have been found unpersuasive.

Applicants' arguments for the dependent claims refer back to those arguments addressed

above regarding the independent claims.

Response to Arguments – 35 USC § 103

2.   In response to the rejection of claims 1-3, 5-7, 9-10, 14, 112-113; 16-18, 20-22, 24-25,

29, 114-115; 31-37, 41, 116-117; 54, 56, 58-60, 62-63, 67-68, 118; 70, 72, 74-76, 78-79, 83-84;

86, 88-92, 96-97, and 119 under 35 U.S.C. § 103 as unpatentable over "Balloon-Artery

Interactions During Stent Placement : A Finite Element Analysis Approach to Pressure,

Compliance, and Stent Design as Contributors to Vascular Injury" by Campbell Rogers, David

Y. Tseng, James C. Squire, and Elazer R. Edelman (hereafter referred to as Rogers) in view of

US Patent No. 5,594,651 to St. Ville, Applicants argue primarily that:

[The Rogers reference fails to teach the claimed limitation "simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device."] Rogers explains in the left hand column of page 379 that "[o]ur model included input of the following: individual stent-strut width and thickness and interstrut distances of the corrugated-ring and slotted-tube stents described above, ... The relationship of the balloon-artery contact stress and the contact area with the distance between 2 adjacent stent struts, balloon materials and inflation pressure was analyzed." Rogers teaches simply calculating the relationship of the contact stress and contact area of the balloon and artery. Rogers does not simulate an interaction between the said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device.

The Examiner respectfully traverses this argument as follows.

Rogers teaches:

The FEA model used in this analysis included both displacement and pressure loading to represent arterial displacement and balloon extrusion between the struts, respectively. (page 379, left column)

Constant step-time functions were used to control artery displacement and balloon extrusion between struts during analysis. The correlations of maximum contact stress and contact area with balloon pressure and the distance between adjacent stent struts at different Young's moduli of balloon materials were analyzed. (page 379, left column, teaching what is input into the finite element analysis)

FEA was used to investigate in a continuous fashion independent effects of distance between stent struts, balloon-material properties, and balloon inflation pressures **on balloon-artery surface stress and contact area**. (page 380, right column, emphasis added)

Therefore Rogers teaches "simulating interaction [using FEA to investigate in a continuous fashion] between the said anatomical features and said medical device [balloon-artery surface stress and contact area] to determine the predicted stresses, strains, and deformations of said medical device [using FEA].

Applicants' arguments have been fully considered but have been found unpersuasive.

Applicants' arguments for the dependent claims refer back to those arguments addressed above regarding the independent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.   Claims 1, 16, 31, 54, 70, and 86 are rejected under 35 U.S.C. 102(b) as being anticipated

by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element

Models" by Santosh G. Zachariah and Joen E. Sanders (hereafter referred to as Zachariah).

Regarding claims 1 and 16, Zachariah discloses:

A system for analyzing medical devices [*"This review addresses FE modeling of

interface stresses in lower-limb external prosthetics."* (abstract)] comprising:

A geometry generator that receives three-dimensional volumetric data of at least one

anatomical feature and generates a geometric model of said anatomical feature(s) [*"To **generate**

the model, the geometry of the object of interest is first discretized into small regularly-shaped

polygonal finite elements; the elements altogether make up the **FE mesh**."* (page 289, right

column, second paragraph, emphasis added); *"In the case of a limb-socket model for the below-

knee (BK) amputee, **the geometric model** typically extends from the mid-thigh to the distal end of

the socket, **incorporating the skeleton and musculature of the residual limb, and the liner (if

one is used) and shell of the prosthetic socket**."* (page 289, right column, third paragraph,

emphasis added)]

A mesh generator that receives said geometric model of said anatomical feature(s) and a

geometric model of a medical device, and generates a finite element model or mesh representing

both of said geometric model of said anatomical feature(s) and said geometric model of said

medical device (*id.*); and

A stress/strain/deformation analyzer that receives said finite element model or mesh,

material properties of said anatomical feature(s) and said medical device, load data on said

anatomical feature(s) and/or said medical device and simulates an interaction between said

anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*"Of particular interest to the design of prosthetic sockets are the* **interface stresses** *between the residual limb and the socket."* (page 289, right column, last paragraph, emphasis added); *"Properties, such as* **stress behavior under strain***, are then assigned to each element. Finally external forces and* **displacements** *and internal constraints – collectively called the boundary conditions – are applied at appropriate nodes within the mesh. The solution of the FE model corresponds to the minimization of a potential energy functional of all the nodal displacements, simultaneously considering the interaction of every element with its neighbors."* (page 289, right column, second paragraph, emphasis added)].

Further regarding claim 31, Zachariah discloses the limitations reiterated from claims 1 and 16, and further discloses an *in vitro* anatomical feature as recited [*"In the case of a limb-socket model for the below-knee (BK) amputee,* **the geometric model typically extends from the mid-thigh to the distal end of the socket***, incorporating the skeleton and musculature of the residual limb, and the liner (if one is used) and shell of the prosthetic socket."* (page 289, right column, third paragraph, emphasis added)].

Further regarding claims 54 and 70, which recite the methods performed by the systems of claim 1 and 16, Zachariah discloses those systems and similarly the method performed by those systems.

Further regarding claim 86, which recites the method performed by the system of claim 31, Zachariah discloses the system of claim 31 and similarly the method performed by that system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

4.   Claims 1-3, 5-7, 9-10, 14, 112-113; 16-18, 20-22, 24-25, 29, 114-115; 31-37, 41, 116-

117; 54, 56, 58-60, 62-63, 67-68, 118; 70, 72, 74-76, 78-79, 83-84; 86, 88-92, 96-97, and 119 are

rejected under 35 U.S.C. 103(a) as being unpatentable over "Balloon-Artery Interactions During

Stent Placement : A Finite Element Analysis Approach to Pressure, Compliance, and Stent

Design as Contributors to Vascular Injury" by Campbell Rogers, David Y. Tseng, James C.

Squire, and Elazer R. Edelman (hereafter referred to as Rogers) in view of US Patent No.

5,594,651 to St. Ville.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, Rogers teaches a system for

analyzing medical devices [*"...we have used finite element analysis to model how balloon-artery*

contact stress and area depend on stent-strut geometry, balloon compliance, and inflation

pressure. " (abstract)], comprising:

A stress/strain/deformation analyzer [*"Automatic Dynamic Incremental Nonlinear*

Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon

Graphics)" (page 379, left column, "Finite Element Analysis")] that receives a finite element

model or mesh, material properties of an anatomical feature(s) and a medical device, load data

on said anatomical feature(s), and/or said medical device [*"Our model included input of the*

following: individual stent-strut width and thickness and interstrut distances of the corrugated-

ring and slotted-tube stents described above, Young's modulus and Poisson's ration for the

balloon material, arterial-wall thickness, Young's modulus (circumferential) and Poisson's ratio

for the artery, and pressure loaded into the balloon. " (page 379, left column, "Finite Element

Analysis")] and simulates an interaction between said anatomical feature(s) and said medical

device to determine the predicted stresses, strains, and deformations of said medical device

[*"The FEA model used in this analysis included both displacement and pressure loading to represent arterial displacement and balloon extrusion between the struts, respectively."* (page 379, left column); *"Constant step-time functions were used to control artery displacement and balloon extrusion between struts during analysis. The correlations of maximum contact stress and contact area with balloon pressure and the distance between adjacent stent struts at different Young's moduli of balloon materials were analyzed."* (page 379, left column); *"FEA was used to investigate in a continuous fashion independent effects of distance between stent struts, balloon-material properties, and balloon inflation pressures on balloon-artery surface stress and contact area."* (page 380, right column, "Finite Element Analysis"); Figure 4; etc.].

Rogers does not expressly teach the claimed geometry generator and mesh generator.

St. Ville teaches a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry ... is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below."* (column 9, lines 31-38)]; and

A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh representing

both of said geometric model of said anatomical features and said geometric model of said medical device [*"A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area."* (column 17, lines 4-6); FIGS. 4A, 4B].

Rogers and St. Ville are analogous art because both are directed to the application of finite element analysis in medical prosthetics.

It would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Rogers and St. Ville to arrive at the claimed invention because St. Ville expressly teaches that the methods taught therein quickly produce the required models for analysis [*"The use of such computer aided design software packages permits a geometric model of an object or part to be defined by a user and modified quickly and results in generation of geometry data which can be converted to formats useful in a computer aided manufacturing step and/or to formats useful to a finite element method step, which steps are discussed in greater detail below."* (column 9, lines 22-28); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip... This image data may be converted to a format usable by the CAD software package or may be directly converted to a format usable by a finite element software package... "* (column 9, lines 31-38)]. Therefore, it would have been obvious to a person of ordinary skill in the art to use the teachings of St. Ville to generate a geometric model and a finite element model or mesh to quickly acquire the necessary models for the simulation method taught by Rogers.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Rogers and St. Ville to arrive at the invention specified in claim 1.

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville teaches that the geometric model of said anatomical features is an idealized geometric model [*"First, a finite element model of the normal bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals..."* (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90, Rogers teaches that the prosthesis is an endovascular prosthesis, a stent graft, and a cardiovascular stent (abstract).

Regarding claims 9, 24, 36, 62, 78, and 91, St. Ville teaches that the mesh generator includes three-dimensional finite modeling software [*"Other suitable software packages for generating the finite element model include MSC/NASTRAN [...], ABAQUS [...], and ANSYS [...]."* (column 9, lines 54-59)].

Regarding claims 10, 25, 37, 63, 79, and 92, Rogers teaches that the stress/strain/deformation analyzer is a non-linear finite element modeling software [*"Automatic Dynamic Incremental Nonlinear Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon Graphics)"* (page 379, left column, "Finite Element Analysis")].

Regarding claims 67, 83, 96, 112, 114, and 116, Rogers teaches that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses strains, and deformations of said medical device [*"Automatic Dynamic Incremental Nonlinear Analysis software (ADINA 7.0, ADINA R&D, Inc) on a dedicated workstation (Silicon Graphics)"* (page 379, left column, "Finite Element Analysis")].

Regarding claims 14, 29, 41, 68, 84, and 97, Rogers teaches a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation (Figure 4).

Regarding claims 113, 115, 117, 118, and 119, St. Ville teaches that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [*"mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

5.   Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

Rogers in view of St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure."* (column 7, lines 8-14)].

Rogers in view of St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling

system of Rogers in view of St. Ville because DiGioia expressly teaches how to provide for the

proper placement and implantation of the joint components to provide an improved range of

motion and usage of the joint following joint reconstruction, replacement, and revision surgery

(DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed

above. These claims are rejected for rationale similar to that given above for claim 4.

6.   Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over

Rogers in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of

"Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by

Seung Lee et al. (Lee).

Rogers in view of St. Ville does not expressly disclose that the geometry generator is a

software application which generates surface points from the three-dimensional volumetric data,

which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo

measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-

lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and

right columns).

Rogers in view of St. Ville and Lee are analogous art because both are directed to

imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of

Applicants' invention to combine the use of MIMICS to interpret MRI data and generate

geometry as taught by Lee in the modeling system of Rogers in view of St. Ville because Lee

expressly teaches that "the goal of this study was to develop an automated mesh generation

technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column)

and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed

above. These claims are rejected for rationale similar to that given above for claim 8.

7.   Claims 11-12, 26-27, 38-39, 64-65, 80-81, and 93-94 are rejected under 35 U.S.C. §

103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 9-10, 24-25,

36-37, 62-63, 78-79, and 91-92 above, and further in view of "Computational Mechanics Moves

Ahead" by Peter J. Raboin (Raboin).

Regarding claim 11, Rogers in view of St. Ville does not expressly disclose that the

three-dimensional finite modeling software tessellates a geometric model into hexahedron brick

elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page

2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two

Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying

dynamic, finite deformations, [which] can model the behavior of joint tissues and bones

subjected to different loads and joint movement with and without prosthetic implants (pages 6-7

of 13).

Rogers in view of St. Ville and Raboin are analogous art because both are directed to

modeling of prosthetic joints.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of Rogers in view of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 26, 38, 64, 80, and 93 reiterate the limitations of claim 11 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 11.

Claims 12, 27, 39, 65, 81, and 94 have been previously interpreted as recited features inherent in DYNA3D and NIKE3D and are therefore rejected for rationale similar to that given above for claim 11. (See Office Action, 7 February 2006, page 5)

8.   Claims 15, 30, 42, 69, 85, and 98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view St. Ville as applied to claims 14, 29, 41, 68, 84, and 97 above, and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey).

Rogers in view St. Ville does not expressly disclose the use of interactive software for visualizing finite element analysis results of three-dimensional grids.

Dovey teaches that GRIZ is "a general-purpose post-processing application supporting interactive visualization of finite element analysis results on unstructured grids. GRIZ calculates and displays derived variables for a variety of analysis codes. Currently, GRIZ works with the family of Methods Development Group (MDG) analysis codes, including DYNA3D, NIKE3D,

and TOPAZ3D." (page 1, "Introduction"). Dovey teaches that GRIZ displays the results of various parameters (page 21, "Results Command"), including various stress results variables (*ex.* "sx", page 21); strain variables (*ex.* "ex", page 22); and deformation (*ex.* "dispx", page 24).

Rogers in view of St. Ville and Dovey are analogous art because both are directed toward finite element analysis.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use GRIZ as taught by Dovey to visualize the results of the modeling system of Rogers in view of St. Ville because Dovey expressly teaches that "GRIZ provides flexible control of mesh materials on an individual basis, allowing the user to concentrate analysis and visual focus on important subsets of the mesh. GRIZ incorporates the ability to animate all representations over time," thereby enhancing the analysis capabilities present in the system taught by Rogers in view of St. Ville to increase productivity.

Claims 30, 42, 69, 85, and 98 reiterate the limitations of claim 15 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 15.

9.   Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rogers in view of St. Ville as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, Rogers in view of St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles... Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed..."* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

Rogers in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Rogers in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, Rogers in view of St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate... This result corresponds more*

closely to the fractographic findings [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations..."* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the* in vitro *data were simply evaluated..."* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

Rogers in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of

Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling

system of Rogers in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures

provide valuable information for improving the design of components and in validating

laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby

improving the effectiveness and reliability of the final designs.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The
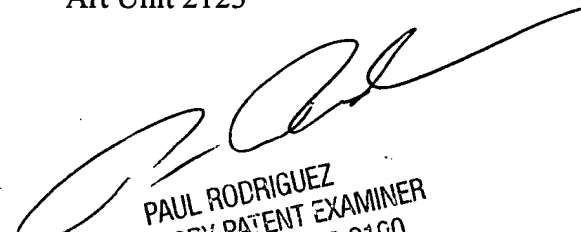
examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Proctor
Examiner
Art Unit 2123

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